

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES**

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| In re Patent Application of: |) | |
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| Application No.: 10/027,154 |) | Art Unit: 3736 |
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| Filed: December 20, 2001 |) | Examiner: Jonathan M. Foreman |
| |) | |
| For: Pressure-Sensing Guidewire and Sheath |) | |
| |) | |

REPLY BRIEF

Mail Stop Appeal Brief - Patents
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

In response to the Examiner's Answer dated December 12, 2007, Appellant respectfully requests that the following reply brief and its arguments be considered by the Board.

With respect to claim rejections, claims 10, 13, and 16 stand rejected under 35 U.S.C. 103(a) as being obvious over U.S. Patent No. 4,168,703 ("Kenigsberg") in view of U.S. Patent Application Publication No. 2002/0049402 ("Peacock, III"); and claims 14 and 19 stand rejected under 35 U.S.C. 103(a) as being obvious over Kenigsberg in view of Peacock, and further in view of U.S. Patent No. 6,259,938 ("Zarychta").

Appellant has previously submitted that all currently pending claims rise and fall with independent claim 10 of the instant application; if the prior art references cited by the Examiner fail to render claim 1 obvious, it cannot render any of the pending dependent claims 13-14, 16, and 19 obvious.

First, in response to Appellant's argument that the combination of Kenigsberg and Peacock, III fails to teach or suggest a tubular sheath having a *closed* distal end, the Examiner maintains that "Kenigsberg discloses the distal end [of the tubular sheath] 'preferably open', but does not teach away from a closed distal end having an opening adjacent thereto" (page 6 of the Examiner's Answer). The Examiner further maintains that it would have been obvious to one of ordinary skill in the art to modify the open distal end of the tubular sheath (12) to be a closed distal end with an opening adjacent thereto because: (a) the elongated tube (22) as well as the tubular members (32, 38) could each have a closed distal end with an opening adjacent thereto; and (b) it is desirable to keep the elongated tube from extending past the distal end of the sheath (pages 6-7 of the Examiner's Answer).

Appellant disagrees. The mere fact that the elongated tube (22) and tubular members (32, 38) can be modified to have closed distal ends with openings adjacent thereto does not constitute a teaching or suggestion of the same modification to the tubular sheath (12), which is structurally and functionally different from the elongated tube (22) and tubular members (32, 38). The sheath (12) is purported to provide a stationary exterior cover for the elongated tube (22) so that the movement of the elongated tube (22) along the gastroesophageal track (44) can be accomplished without disturbing the patient or affecting the accuracy of the pressure readings at various selected positions within the gastroesophageal track (44) (col. 5, lines 52-61). Unlike the elongated tube (22) and tubular members (32, 38), no water is infused *through* the sheath (12). Nor is the sheath (12) connected to any pressure measuring gauge. Appellant respectfully submits that a specific modification of one type of component cannot be properly transferred or extrapolated to another structurally and functionally distinct component without any teaching or suggestion from the prior art or any motivation apparent to one of ordinary skill in the art.

The Examiner further maintains that the modification of the distal end of Kenigsberg's sheath (12) is obvious because Kenigsberg teaches that it is desirable to keep the elongated tube from extending past the distal end of the sheath (col. 3, lines 28-31). By not offering any counter argument in the Answer, the Examiner appears to have agreed with Appellant that the overextension of the elongated tube is conveniently solved by sizing the length of the elongated tube, but nevertheless maintains that closing the distal end of the tubular sheath (12) is another solution known in the art. However, Appellant respectfully submits that a modification merely "known in the art" is not sufficient in establishing a *prima facie* case of obviousness unless there is motivation to make such a modification. The closing of the distal end of the sheath (12) to solve the overextension problem is neither contemplated by Kenigsberg, nor *motivated* by the common knowledge in the art because the overextension is already conveniently prevented by sizing the length of the elongate tube (22).

Thus, contrary to the Examiner's assertion, the modification of the distal end of the sheath proposed by the Examiner is not disclosed or suggested by Kenigsberg. Nor is the modification properly inferred from the broadest interpretation of Kenigsberg's disclosure by one of ordinary skill in the art. As a result, Appellant maintains that the cited prior art does not teach or suggest a tubular sheath having a closed distal end, as recited in independent claim 10.

Second, the Examiner maintains that the distal portion of Kenigsberg's device may be modified in view of Peacock, III to have an exterior surface with a cross-sectional profile of a single circle. Again, the Examiner's assertion is based merely on Kenigsberg's disclosure that "the member 32 may be located *within* a suitably modified sheath" (col. 3, lines 62-63, emphasis added by Appellant). The Examiner has conceded that the two possible

configurations of such modification submitted by Appellant in the Appeal Brief would lead to inoperability of Kenigsberg's device. Nevertheless, the Examiner maintains that a third configuration in view of Peacock, III, in which the tubular member (32) is provided as a lumen in the sidewall of the sheath, is a valid and operable modification of Kenigsberg.

Appellant disagrees. According to Kenigsberg, the tubular member (32) may be located *within* the sheath. Appellant submits that the plain meaning of "within the sheath" is "within the interior of the sheath". This interpretation is also adopted by Kenigsberg throughout its disclosure. *See* col. 3, line 20; and col. 5, lines 4 and 53 of Kenigsberg. The modification suggested by the Examiner, on the other hand, is to locate the tubular (32) within the sidewall of the sheath, which is entirely different from the location contemplated by Kenigsberg.

Further, the Examiner appears to have maintained that the rationale behind the suggested modification is to lead to operability of the device as well as the outside peripheral surface of the elongated tube engaging the inside peripheral surface of the tubular sheath.

Appellant again respectfully disagrees. Kenigsberg's device is perfectly operable. And the limitation of "the outside peripheral surface of the elongated tube engaging the inside peripheral surface of the tubular sheath" is a requirement for the operability of Kenigsberg's device, and not a motivation to modify the device in the first place. Thus, it is clear that the modification suggested by the Examiner is motivated not by the cited prior art or knowledge in the field of invention, but by the impermissible hindsight reasoning prohibited by the patent laws.

Third, Appellant maintains that the modification of Kenigsberg in view of Peacock, III is oversimplified by the Examiner, presumably in order to make such modification within

the reach of one having ordinary skill in the art. The tubular member (32) is not a simple lumen because “[m]ember 32 is an elongated, hollow tube” (col. 3, lines 58-59) with a proximal end that “extends flexibly *away* from the sheath 12” (col. 4, lines 2-3, emphasis added by Appellant). As a result, the incorporation of the member (32) into the tubular wall of sheath (12) proposed by the Examiner would require extensive modification of the structure and shape of the sheath (12). Further, the diameter of the tubular member (32) would need to be decreased substantially in order to accommodate the modification proposed by the Examiner. A person of ordinary skill in the art would not attempt to position the tubular member (32) within the tubular wall of the sheath (12) by substantially shrinking the diameter of the tubular member (32) and extensively modifying the sheath (12) without any motivation and guidance from Kenigsberg.

Finally, Appellant has previously argued in the Appeal Brief that the combination of Kenigsberg and Peacock, III is improper because neither of the references is in the same or reasonably pertinent field of this application. However, this argument is ignored by the Examiner in the Answer. Appellant hereby maintains the same argument and respectfully invites the Examiner to address this issue. Otherwise, withdrawal of the rejection based on the combination of Kenigsberg and Peacock, III is respectfully requested.

In light of the foregoing, Appellant respectfully submits that the appealed rejections are improper and must be reversed by the Board of Appeals because a *prima facie* case of obviousness is not established by the combination of the references proposed by the Examiner and because none of the reference relied upon by the Examiner in making the appealed rejections is within the same or reasonably pertinent field of this application.

Dated: February 8, 2008

Respectfully submitted,

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